5 510(K) SUMMARY

APR - 7 2010

Applicant:

Ethicon Inc.
P.O. Box 151
Route 22 West
Somerville, NJ 08876
USA
Phone: +1-908-218-2954
Fax: +1-908-218-2595

Date: November 25, 2009

Contact Person: Joseph Kiceina

Proprietary Device Name: ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device

Common Device Name: Implantable staple; 21CFR 878.4750

Classification: GDW; Class II

Predicate Devices: AbsorbaTack™ Absorbable Fixation Device (K091900)

Manufacturer:

Ethicon LLC
Guaynabo, Puerto Rico 00969
USA

5.1 Substantially Equivalent To:

The ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device is substantially equivalent to the Covidien AbsorbaTack™ Absorbable Fixation Device (K091900).

The ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device has the same intended use, and similar indications for use, technological characteristics, and principles of operation as its predicate device.

The minor technological differences between the ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device and the AbsorbaTack™ Absorbable Fixation Device raise no new issues of safety or effectiveness as verified by performance data.

5.2 Description of the Device Subject to Premarket Notification:

The ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device is a 5mm laparoscopic device for hernia repair. It is a multi-fire, single–use device pre-loaded with 25 absorbable straps. The straps are composed of a blend of polydioxanone and L(-)-lactide and glycolide dyed with D&C Violet No. 2.

5.3 Indications for Use:

The ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repairs.

5.4 Performance Data:

An appropriate and complete performance testing program, including bench and animal, supports that the ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device fulfills the device requirements as defined in used specifications, functions as intended, and is substantially equivalent to the predicate device.

5.5 Overall Performance Conclusion:

An appropriate and complete performance testing program, including bench and animal testing was performed. Results support that the ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device meets the device requirements as defined in user specifications, functions as intended, and is substantially equivalent to the predicate device. The materials that are used in the manufacturing of this device have been evaluated in accordance with ISO 10993-1:2003, Biological Evaluation of Medical Devices – Part 1 Evaluation and Testing and are equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR - 7 2010

Ethicon Inc.
% Mr. Joseph Kiceina
Manager, Regulatory Affairs
P.O. Box 151, Route 22 West
Somerville, New Jersey 08876

Re: K093845
Trade/Device Name: Ethicon SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: March 31, 2010
Received: April 01, 2010

Dear Mr. Kiceina:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 INDICATIONS FOR USE STATEMENT

510(k) No (if known): _____

Device Name: ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device

Indications for Use:
The ETHICON SECURE*STRAP*™ 5mm Absorbable Strap Fixation Device is intended for fixation of prosthetic material to soft tissues in various minimally invasive and open surgical procedures such as hernia repair.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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David Krause for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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